

Protocol Title: Comparative study between behavior therapy and
behavior therapy plus mirabegron 50mg in
sexually active men with bothersome overactive
bladder symptoms – A multicenter, randomized
study

IRB No.: 202000790A3

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3. STATISTICAL ANALYSIS

3.1. Number and Source

This study will be conducted at Kaohsiung Chang Gung Memorial Hospital, and 4 other medical centers. Approximately 150 patients will be enrolled and completed within the two-year study period.

The study is designed as a comparative study between (1) behavior therapy group and (2) behavior therapy plus mirabegron group in a 1:2 ratio.

Based on our previous publication [PubMed ID: 31567878], the IIEF-5 score decreased from 16.4 ± 5.5 to 15.6 ± 5.6 ($p = 0.106$) and 14.9 ± 5.9 ($p = 0.077$) at 4-week and 12-week follow-up, respectively. Group sample sizes of 78 and 37 achieve 80% power to detect a difference of 2.600 in a design with 3 repeated measurements having a Compound Symmetry covariance structure when the standard deviation is 5.600, the correlation between observations on the same subject is 0.500, and the alpha level is 0.050. With 30% drop out rate, the estimated sample size would be around 150.

3.2 Statistical Methods

Data will be expressed as mean with SD for continuous variables or as n with percentage for categorical variables. Changes in symptom scores, uroflowmetry parameters and PVR volume from baseline to every visit after treatment initiation will be compared with the generalized estimated equation. The treatment responses in each subgroup will also be analyzed with generalized estimated equation. The level of significance is considered as $p < 0.05$.

REFERENCE

Wu TH, Shen YC, Lee WC, Wang HJ, Chuang YC. Effect of mirabegron on erectile function in sexually active men with bothersome overactive bladder symptoms. J Chin Med Assoc. 2020 Jan;83(1):55-59. doi: 10.1097/JCMA.000000000000208. PubMed ID: 31567878